RULES
OF
THE TENNESSEE DEPARTMENT OF HEALTH
DIVISION OF HEALTH CARE FACILITIES

CHAPTER 1200-8-12
TRAUMA CENTERS

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1200-8-12-.01 PREAMBLE. The Tennessee Department of Health is empowered to adopt such regulations and standards pertaining to the operation and management of hospitals as are necessary for the public interest. On November 24, 1982, a resolution was prepared by the EMS Advisory Council and presented to the Board of Licensing Health Care Facilities recommending that a formal review of the issues involved in the designation of trauma centers for the State of Tennessee be explored. Subsequently, on February 17, 1983, a presentation was requested of the City of Memphis Hospital Trauma Center by the Board in an effort to further define the need for action on trauma center designation and/or categorization. As a result of that presentation, a Task Force was created by the Board for licensing health care facilities to evaluate and recommend criteria concerning the development of trauma systems and for the operation of trauma centers in the state.

Authority: *T.C.A. §68-11-201 et seq.* ***Administrative History:*** *Original rule filed September 18, 1985; effective October 18, 1985.*

1200-8-12-.02 AUTHORITY. These regulations are issued under the authority granted the Health Care Facilities Licensing Board at T.C.A. 68-11-201 et seq.

Authority: *T.C.A. §68-11-201 et seq.* ***Administrative History:*** *Original rule filed September 18, 1985; effective October 18, 1985.*

1200-8-12-.03 DEFINITIONS.

(1) "Levels of Care" shall mean the type of trauma service provided by the institution as shown by the degree of commitment in personnel and facilities made to the delivery of that service.

(2) "Level I" shall designate that institution committed to providing optimum care for the acutely injured patient which meets all requirements in this regulation defined as Level of Care I.

(3) "Level II" shall designate an institution committed to providing optimum care for the acutely injured that meets the requirements in this regulation defined as Level of Care II.

(4) "Level III" the Level III hospital generally serves communities that do not have all the resources usually associated with Level I or II institutions. However, a Level III hospital reflects a maximum commitment to trauma care commensurate with resources. Planning for care of the injured in small communities or suburban settings usually calls for transfer agreements and protocols for the most severely injured. Designation of the Level III hospital may also require innovative use of the region's resources. For example, if there is no neurosurgeon in a large, sparsely populated region it may require that a general surgeon be prepared to provide the emergency decompression of mass lesions. Transfer to the most appropriate Level I or II hospital can then be arranged after the patient's life-saving operation has been carried out. Another example is the staffing of the Level III hospital. In many instances it will be impractical to require a general surgeon to be in-house. With modem communication systems it seems reasonable that the surgeon should be promptly available and in a

(Rule 1200-8-12-.03, continued)

great majority of instances meet the patient in the emergency room on arrival. On-call personnel such as laboratory, x-ray, and operating room nurses also can be activated and respond promptly to the hospital when the first notification of a critically injured patient is received. The intent of this flexibility should be clear: to provide the best possible care even in the most remote circumstances.

Authority: *T.C.A. §§68-11-201 et seq. and 4-5-202.* ***Administrative History:*** *Original rule filed September 18, 1985; effective October 18, 1985. Amendment filed March 31, 1989; effective May 15, 1989.*

1200-8-12-.04 REQUIREMENTS.

(1) ***Levels of Care***

(a) *Hospital Origination*

		Levels	
		I	*II*
1.	Trauma Service	X	X
2.	Surgery Departments/Divisions/Services/Sections (each staffed by qualified specialists)		
	Cardiothoracic Surgery	X	X[1]
	General Surgery	X	X
	Neurologic Surgery	X	X
	Obstetrics-Gynecologic Surgery	X	
	Ophthalmic Surgery	X	
	Oral and Maxillofacial Surgery-Dentistry	X	
	Orthopaedic Surgery	X	X
	Otorhinolaryngologic Surgery	X[3]	
	Pediatric Surgery	X[4]	
	Plastic Surgery	X[3]	
	Urologic Surgery	X	
3.	Emergency Department/Division/Service/ Section (staffed by qualified specialists)	X[5]	X[5]
4.	Surgical Specialties Availability In-house 24 hours a day		
	General Surgery	X[6]	
	Neurologic Surgery	X[7]	
	On-call and available from inside or outside hospital		
	Cardiac Surgery	X	X[1]
	General Surgery		X [17]

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	Levels	
	I	*II*
Neurologic Surgery		X[17]
Microsurgery Capabilities	X	
Gynecologic Surgery	X	
Hand Surgery	X	
Ophthalmic Surgery	X	X
Oral and Maxillofacial Surgery-Dentistry	X	X
Orthopaedic Surgery	X	X
Otorhinolaryngologic Surgery	X	X
Pediatric Surgery	X[4]	X[4]
Plastic Surgery	X	X
Thoracic Surgery	X	X
Urologic Surgery	X	X

5. Non-Surgical Specialties Availability

In-hospital 24 hours a day:

Emergency Medicine	X[8]	X[8]
Anesthesiology	X[10]	X[11]

On-call and available from inside or outside hospital:

Cardiology	X	X
Chest (Pulmonary) Medicine	X	
Gastroenterology	X	
Hematology	X	
Infectious Diseases	X	
Internal Medicine	X	X
Nephrology	X	X
Pathology	X[12]	X[12]
Pediatrics	X	X
Psychiatry	X	X
Radiology	X	X

(b) *Special Facilities/Resources/Capabilities*

1. Emergency Department

(i) Personnel

(I) Designated Physician Director	X	X
(II) Full time emergency department; department; RN personnel 24 hours a day	X	X

(ii) Equipment for resuscitation and to provide support for the critically or seriously injured must include but shall not be limited to:

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			Levels I	*Levels* II
	(I)	Airway control and ventilation equipment including laryngoscopes and endotracheal tubes of all sizes, bag-mask resuscitator, sources of oxygen, and mechanical ventilator	X	X
	(II)	Suction devices	X	X
	(III)	Electrocardiograph-oscillo-scope-defibrillator	X	X
	(IV)	Apparatus to establish central venous pressure monitoring	X	X
	(V)	All standard intravenous fluids and administration devices, including intravenous catheters	X	X
	(VI)	Sterile surgical sets for procedures standard for ED, such as thoracostomy, cutdown, etc.	X	X
	(VII)	Gastric lavage equipment	X	X
	(VIII)	Drugs and supplies necessary for emergency care; splinting materials	X	X
	(IX)	X-ray capability, 24-hour coverage by in-house technicians	X	X
	(X)	Two-way radio linked with vehicles of emergency transport system	X	X
	(XI)	Pneumatic Anti-Shock Garment*	X	X
	(XII)	Skeletal Tongs	X	X
	(XIII)	Cervical collars*	X	X
2.	Intensive Care Units (ICU) for Trauma Patients			
	(i)	Designated Medical Director	X	X
	(ii)	Physician on duty in ICU 24-hours a day or immediately available from in-hospital	X	X

(Rule 1200-8-12-.04, continued)

			Levels I	II
(iii)	Nurse-patient minimum ratio of 1:2 on each shift		X	X
(iv)	Immediate access to clinical laboratory services		X	X
(v)	Equipment:			
	(I)	Airway control and ventilation devices	X	X
	(II)	Oxygen source with concentration controls	X	X
	(III)	Cardiac emergency cart	X	X
	(IV)	Temporary transvenous pacemaker	X	X
	(V)	Electrocardiograph-osciloscope-defibrillator	X	X
	(VI)	Cardiac output monitoring	X	X
	(VII)	Electronic pressure monitoring	X	X
	(VIII)	Mechanical ventilator-respirators	X	X
	(IX)	Patient weighting devices	X	X
	(X)	Pulmonary function measuring devices	X	X
	(XI)	Temperature control devices	X	X
	(XII)	Drugs, intravenous fluids and supplies	X	X
		*Needed also as supply replacement time for EMS crews		
	(XIII)	Intracranial pressure monitoring devices	X	X
3.	Postanesthetic Recovery Room (PAR) (intensive care unit is acceptable)			
(i)	Registered nurses 24-hours a day		X	X
(ii)	Monitoring and resuscitation equipment		X	X
4.	Acute Hemodialysis Capability		X	X[13]

(Rule 1200-8-12-.04, continued)

				Levels *I*	*II*
	5.	Organized Burn Care		X[14]	X[14]
		(i)	Physician-directed Burn Center/Unit staffed by nursing personnel trained in burn care and equipped properly.		
	6.	Radiological Special Capabilities			
		(i)	Angiography of all types	X	X
		(ii)	Sonography	X	X
		(iii)	Nuclear scanning	X	X
		(iv)	In-house computerized tomography	X	X
	7.	Organ donation protocol		X[15]	X[15]
(c)	*Operating Suite Special Requirements*				
	1.	Equipment-instrumentation:			
		(i)	Operating room, dedicated to the trauma service, with nursing staff in-house and immediately available 24-hours a day	X	X
		(ii)	Cardiopulmonary bypass capability	X	
		(iii)	Operating microscope	X	X
		(iv)	Thermal control equipment	X	X
		(v)	X-ray capability	X	X
		(vi)	Endoscopes, all varieties	X	X
		(vii)	Craniotomy instrumentation	X	X
		(viii)	Monitoring equipment	X	X
			(I) for patient	X	X
			(II) for blood	X	X
(d)	*Clinical Laboratories Services available 24 hours a day*				
	1.	Standard analyses of blood, urine, and other body fluids		X	X

(Rule 1200-8-12-.04, continued)

			Levels I	II
	2.	Blood typing and cross-matching	X	X
	3.	Coagulation studies	X	X
	4.	Blood bank or access to a community central blood bank and hospital storage facilities	X	X
	5.	Blood gases and pH determinations	X	X
	6.	Serum and urine osmolality	X	X
	7.	Microbiology	X	X
	8.	Drug and alcohol screening	X	X
(e)	*Programs for Quality Assurance*			
	1.	Medical care education including:		
		(i) Trauma death audit review.	X	X
		(ii) Morbidity and mortality review.	X	X
		(iii) Trauma conference, multidisciplinary.	X	X
		(iv) Trauma bypass log.	X	X
		(v) Medical records review	X	X
	2.	OUTREACH PROGRAM: telephone and on-site consultations with physicians of the community and out-lying areas	X	
	3.	PUBLIC EDUCATION: specifically directed towards trauma; for example, injury prevention in the home, industry, and on the highways and athletic fields; standard first-aid; problems confronting public, medical profession, and hospitals regarding optimal care for the injured	X	X
(f)	*Trauma Research Program*			
(g)	*Training Programs in Continuing Education Provided by for:*			
	1.	Staff physicians	X	X
	2.	Nurses	X	X
	3.	Allied health personnel	X	X
	4.	Community physicians	X	X
(h)	*Helipad or Helicopter Landing Area*		X	X

(Rule 1200-8-12-.04, continued)

(2) ***Implementation***

(a) Implementation of the designation process will be by the Licensing Board for Health Care Facilities. A site visit team will be responsible for making recommendations to this Board. Institutions wishing to be designated as Level I or Level II Trauma Centers will make application to the Board. The application may be reviewed by the Site Visit Team and, if appropriate, the team will visit the institution. If the application is felt to be insufficient, this fact will be communicated to the Institution. If the Institution is visited, the team's findings will be documented and submitted to the Board with recommendations. Formal designation will be made by the Board. Designation will be effective for up to five years.

(b) The Site Visit Team will be advisory to the Board, and will consist of the following: The State Medical Director of EMS or the State Director of EMS, a Trauma Surgeon from in-state, a Trauma Surgeon from out-of-state, a Critical Care Nurse from in-state, and a Hospital Director from in-state. These members will act as consultants to the Board, and will be selected with the assistance of the TNA Critical Care Nurses Association, T.H.A., and the National and State Committees on Trauma of the American College of Surgeons.

(c) All costs of the application process, including costs of a site visit, will be borne by the applying institution.

(d) Initially, only Level I applications will be considered. Once a Level I Center has been designated for a region and has achieved optimal utilization or at least one year has elapsed since initial designation, applications for level II designation will be considered, except that those areas which cannot be served adequately by the nearest Level I Trauma Center because of geographic consideration may immediately pursue Level II designation.

(e) All designated Trauma Centers shall participate in the collection of data for the Trauma Registry and in the review of the Trauma Registry.

(f) All designated trauma centers shall record and report the payor source for patient care on discharge, with financial data classed as self pay, commercial insurance, Medicare, Medicaid, or worker compensation.

(3) ***Prohibitions***

(a) It shall be a violation of these regulations for any health care facility to hold out, advertise or otherwise represent itself to be a "trauma center" as licensed by the health care facilities licensing board unless it has complied with the regulations set out herein and has been so licensed by the said board.

(b) Any facility designated by the Board for Licensing Health Care Facilities as a trauma center, at any level, shall provide hospital emergency services to any applicant who applies for the same in case of injury or acute medical condition where the same is liable to cause death or severe injury or illness. The medical need of an applicant and the available medical resources of the facility, rather than the financial resources of an applicant, shall be the determining factors concerning the scope of service provided.

REFERENCES

1. Or substituted by a current signed transfer agreement with Institution with Cardio-Thoradic Surgery and Cardio-Pulmonary bypass capability.

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2. Or substituted by a current signed transfer agreement with Institution with Neurosurgery Department/Division.

3. Or substituted by department or division capable of treating maxillofacial trauma as demonstrated by staff privileges.

4. Or substituted by a current signed transfer agreement with hospital having a pediatric surgical service.

5. The emergency department staffing must provide immediate and appropriate care for the trauma patient. The emergency department physician must function as a designated member of the trauma team.

6. Requirement may be fulfilled by Senior Surgical Resident (P.G.4 or higher) capable of assessing emergency situations in trauma patients initiating proper treatment. A staff surgeon trained and capable of carrying out definitive treatment must be available within 30 minutes.

7. Requirement may be fulfilled by in-house neurosurgeon or neurosurgery resident, or senior general surgery resident who has special competence, as documented by the Chief of Neurosurgery Service, in the care of patients with neural trauma, and who is capable of initiating measures directed toward stabilizing the patient and initiating diagnostic procedures. An attending neurosurgeon dedicated to the hospital's trauma service must be available within 30 minutes.

8. Requirement may be fulfilled by senior level (last year in training) Emergency Medicine Residents capable of assessing emergency situations and initiating proper treatment. The staff specialist responsible for the resident must be available within 30 minutes.

9. Requirement may be fulfilled by a senior level Emergency Medicine Resident or senior level (P.G.4 or above) Surgery Resident.

10. Requirement may be fulfilled by residents capable of assessing emergency situation and initiating proper treatment. A staff anesthesiologist must be available within 30 minutes.

11. (i) Requirement for Level I Trauma Center may be fulfilled when local conditions assure that a staff anesthesiologist will be available within 30 minutes. During the interim period prior to the arrival of a staff anesthesiologist, a Certified Registered Nurse Anesthetist (CRNA) capable of assessing emergency situations in trauma patients and of initiating and providing any indicated treatment must be available in-house.

(ii) Requirement for Level II Trauma Center may be fulfilled when local conditions assure that a staff anesthesiologist is on call and available within 30 minutes. During the interim period prior to the arrival of a staff anesthesiologist, a Certified Registered Nurse Anesthetist (CRNA) operating under the direction of the anesthesiologist, the trauma team surgeon director or the emergency medicine physician, may initiate appropriate supportive care.

(iii) Requirement for Level III Trauma Center may be fulfilled when local conditions assure that a staff anesthesiologist is on call or available within 30 minutes, however, when there is not an anethesiologist on the hospital staff, this requirement may be fulfilled by a Certified Registered Nurse Anesthetist (CRNA) operating

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under the supervision of the surgeon, the anesthesiologist, and/or the responsible physician.

12. Forensic pathologist must be available either as part of the hospital staff or on a consulting basis.

13. Or substituted by current signed transfer agreement with hospital having hemodialysis capabilities.

14. Or substituted by current signed transfer agreement with burn center or hospital with burn unit.

15. Each Level I and Level II Center must have an organized protocol with a transplant team or service to identify possible organ donors and assist in procuring organs for donation.

16. Nursing Staff may be available on-call.

17. All specialists must be available within 30 minutes.

Authority: *T.C.A. §§68-11-209 and 4-5-202.* ***Administrative History:*** *Original rule filed September 18, 1985; effective October 18, 1985. Amendment filed March 31, 1989; effective May 15, 1989. Amendment filed August 31, 1990; effective October 15, 1990. Amendment filed October 20, 1992; effective December 4, 1992. Amendment filed July 21, 1993; effective October 4, 1993.*

1200-8-12-.05 REQUIREMENTS FOR LEVEL III TRAUMA CENTERS.

Essential (E) or Desirable (D)

(1) Hospital Organization

(a) Trauma Service E

1. Specified delineation of privileges for the Trauma Service must be made by the medical staff Credentialing Committee.

2. Trauma team - May be organized by a qualified physician but care must be directed by a general surgeon expert in and committed to care of the injured, all patients with multiple-system or major injury must be initially evaluated by the trauma team, and the surgeon who will be responsible for overall care of a patient (the team leader) identified. A team approach is required for optimal care of patients with multiple-system injuries.

(b) Surgery Department/Divisions/Services/Section (each staffed by qualified specialists)
Cardiothoracic Surgery
General Surgery E
Neurologic Surgery
Obstetrics-Gynecologic Surgery
Ophthalmic Surgery

(Rule 1200-8-12-.05, continued)

Oral Surgery-Dental
Orthopedic Surgery
Otorhinolaryngologic Surgery
Pediatric Surgery
Plastic and Maxillofacial Surgery
Urologic Surgery

(c) Emergency Department/Division/Service/Section
(staffed by qualified specialist) (see note 1) E

(d) Surgical Specialties Available
In-house 24 hours a day:

General Surgery
Neurologic Surgery
On-call and promptly available from inside or outside hospital:
Cardiac Surgery
General Surgery E
Neurologic Surgery D
Microsurgery Capabilities
Gynecologic Surgery
Hand Surgery
Ophthalmic Surgery D
Oral Surgery (dental)
Orthopaedic Surgery D
Otorhinolaryngolgic Surgery D
Pediatric Surgery
Plastic and Maxillofacial Surgery D
Thoracic Surgery D
Urologic Surgery D

(e) Non-Surgical Specialties Availability
In-hospital 24 hours a day:
Emergency Medicine E

Anesthesiology E

On-call and promptly available from inside or outside hospital:
Cardiology D
Chest Medicine
Gastroenterology
Hematology D
Infectious Diseases

1. The emergency department staff should ensure immediate and appropriate care for the trauma patient. The emergency department physician should function as a designated member of the trauma team and the relationship between emergency department physicians and other participants of the trauma team must be established on a local level, consistent with resources but adhering to established standards and optimal care.

(Rule 1200-8-12-.05, continued)

2. Requirements may be fulfilled when local conditions assure that the staff anesthesiologist will be in the hospital at the time or shortly after the patient's arrival in the hospital. In some circumstances this qualification may be met by a certified nurse anesthetist (CRNA) operating under protocol from an anesthesiologist and in consultation with the trauma team surgeon director.

Internal Medicine	E
Nephrology	D
Neuroradiology	
Pathology	D
Pediatrics	D
Psychiatry	
Radiology	D

(2) Special Facilities/Resources/Capabilities

(a) Emergency Department (ED)

1. Personnel

(i) Designated physician director E

(ii) Physician with special competence in care of the critically injured who is a designated member of the trauma team and physically present in the ED 24 hours a day E

(iii) RNs, LPNs, and nurses' aides in adequate numbers E

2. Equipment for resuscitation and to provide life support for the critically or seriously injured shall include but not be limited to:

(i) Airway control and ventilation equipment including laryngoscopes and endotracheal tubes of all sizes, bag-mask resuscitator pocket masks, oxygen, and mechanical ventilator E

(ii) Suction devices E

(iii) Electrocardiograph-oscilloscope defibrillator E

(iv) Apparatus to establish central venous pressure monitoring E

(v) All standard intravenous fluids and administration devices, including intravenous catheters E

(Rule 1200-8-12-.05, continued)

(vi) Sterile surgical sets for procedures standard for ED such as thoracostomy, cutdown, etc. E

(vii) Gastric lavage equipment E

(viii) Drugs and supplies necessary for emergency care E

(ix) X-ray capability, 24-hour coverage by in-house technician E

(x) Two-way radio linked with vehicles of emergency transport system E

(xi) Skeletal traction for cervical injuries E

(b) Intensive Care Units (ICUs) for Trauma Patients
ICUs may be separate specialty units.

1. Designated medical director E

2. Physician on duty in ICU 24 hours a day or immediately available from in-hospital E

3. Nurse-patient minimum ratio of 1:2 on each shift

4. Immediate access to clinical laboratory services E

5. Equipment:

(i) Airway control and ventilation devices E

(ii) Oxygen source with concentration controls E

(iii) Cardiac emergency cart E

(iv) Temporary transvenous pacemaker E

(v) Electrocardiograph-oscilloscope defibrillator E

(vi) Cardiac output monitoring D

(vii) Electronic pressure monitoring D

(viii) Mechanical ventilator-respirators E

(ix) Patient Weighing devices E

(x) Pulmonary function measuring devices E

(xi) Temperature control devices E

(Rule 1200-8-12-.05, continued)

(xii) Drugs, intravenous fluids, and supplies E

(xiii) Intracranial pressure monitoring devices D

(c) Postanesthetic Recovery Room (surgical intensive care unit is acceptable)

1. Registered nurses and other essential personnel 24 hours a day E

2. Appropriate monitoring and resuscitation Equipment E

(d) Acute Hemodialysis Capability (or transfer agreement) E

(e) Organized Burn Care E

1. Physician-directed burn center staffed by nursing personnel trained in burn care and equipped properly for care of the extensively burned patient,
OR

2. Transfer agreement with nearby burn center or hospital with a burn unit

(f) Acute Spinal Cord/Head Injury Management Capability E

1. In circumstances where a designated spinal cord injury rehabilitation center exists in the region, early transfer should be considered; transfer agreements should be in effect

2. In circumstances where a head injury center exists in the region, transfer should be considered in selected patients; transfer agreements should be in effect

(g) Radiological Special Capabilities

1. Angiography of all types D

2. Sonography

3. Nuclear scanning

4. In-house computerized tomography with technician

(h) Rehabilitation Medicine E

1. Physician-directed rehabilitation service staffed by nursing personnel trained in

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rehabilitation care and equipped properly for care of the critically injured patients, OR

2. Transfer agreement when medically feasible to a nearby rehabilitation service

(3) Operating Suite Special Requirements Equipment Instrumentation

(a) Operating room adequately staffed in-house and available 24 hours a day D

(b) Cardiopulmonary bypass capability

(c) Operating microscope

(d) Thermal control equipment:

1. for patient E

2. for blood E

(e) X-ray capability E

(f) Endoscope, all varieties E

(g) Craniotome D

(h) Monitoring equipment

(4) Clinical Laboratory Service (available 24 hours a day)

(a) Standard analyses of blood, urine, and other body fluids E

(b) Blood typing and cross-matching E

(c) Coagulation studies E

(d) Comprehensive blood bank or access to a community central blood bank and adequate hospital storage facilities E

(e) Blood gases and pH determinations E

(f) Serum and urine osmolality D

(g) Microbiology E

(h) Drug and alcohol screening D

Toxicology screens need not be immediately available but are desirable. If not available, results should be included in all quality assurance reviews.

(Rule 1200-8-12-.05, continued)

(5) Quality Assurance

(a) Trauma death audit review. E

(b) Morbidity and mortality review. E

(c) Trauma conference, multidisciplinary. E

(d) Trauma bypass log. E

(e) Medical record review. E

(6) Outreach Program
Telephone and on-site consultation with physicians of the community and outlying areas.

(7) Public Education
Injury prevention in the home and industry, and on the highways and athletic fields; standard first-aid; problems confronting public, medical profession, and hospitals regarding optimal care for the injured.

(8) Trauma Research Program D

(9) Training Program

(a) Formal programs in continuing education provided by hospital for:

1. Staff physicians D

2. Nurses D

3. Allied health personnel D

4. Community physician D

(b) Regular and periodic multidisciplinary trauma conference that include all members of the trauma team should be held. This conference will be for the purpose of quality assurance through critiques of individual cases.

(c) Documentation of severity of injury (by trauma score, age, injury severity score) and outcome (survival, length of stay, ICU lengths of stay) with monthly review of statistics.

(10) Financial Data

(a) All designated trauma centers shall record and report the payor source for patient care on discharge with financial data classed as self pay, commercial insurance, Medicare, Medicaid, or workers compensation.

Authority: *T.C.A. §§68-11-209 and 4-5-202.* ***Administrative History:*** *Original rule filed March 31, 1989; effective May 18, 1989. Amendment filed July 21, 1993; effective October 4, 1993.*